15 de mayo de 2012

VICEPRESIDENTES, RECTORES, VICERRECTORES, DECANOS, FACULTAD Y
COMUNIDAD UNIVERSITARIA DEL SISTEMA UNIVERSITARIO ANA G. MÉNDEZ

ORDEN EJECUTIVA: NÚM. 05-2012

ENMIENDA A ORDEN EJECUTIVA: NÚM. 07-2009
“ANIMAL CARE AND USE COMMITTEE (ACUC) POLICIES AND PROCEDURES
ANIMAL CARE AND USE HANDBOOK”

El Sistema Universitario Ana G. Méndez (SUAGM) está comprometido en desarrollar un
ambiente que fomente el interés en la investigación. Para ello, es necesario continuar proveyendo
una infraestructura de cumplimiento con las regulaciones que rigen las actividades de
investigación, tanto en el salón de clases como en el campo.

Para lograr lo antes descrito se ha establecido el Comité para el Cuidado y Uso de Animales con
representación de las tres instituciones académicas y de la comunidad general para asegurar una
cultura ética y humana en el trato de animales dentro del salón de clases y en su entorno. Además
de proveer una cultura ética, el SUAGM promueve un ambiente de cumplimiento con las
regulaciones federales y estatales.

A tales efectos se enmienda la Orden Ejecutiva 07-2009 (ANIMAL CARE AND USE
COMMITTEE (ACUC) POLICIES HANDBOOK), la cual tiene el propósito de cumplir con
las leyes federales, estatales y políticas institucionales en las que involucran actividades con el
uso de animales, su cuidado, transporte o en la enseñanza.
Dichas enmiendas incluyen:
- Se integra el inciso “No se permite la entrada de animales (vertebrados o invertebrados) en las
facilidades del SUAGM sin aprobación previa. Entre el tipo de animal que se incluyen están las
mascotas, animales de exhibición, actividades que incluyan animales, entre otras”.

- El título de la Política “Animal Care and Use Committee (ACUC) Policies and Procedures
Animal Care and Use Handbook” leía “Animal Care and Use Policies and Procedures” para
que refleje la totalidad de los procesos de Cuidado y Uso de Animales en el SUAGM.

-Se actualizó las referencias en la política utilizando las nuevas guías para el Cuidado y Uso de
Animales según adoptada por el NIH (8va edición 2011)

Mediante la presente Orden Ejecutiva 05-2012, apruebo la enmienda a la política de “ANIMAL
CARE AND USE POLICIES AND PROCEDURES” y declaro su efectividad e implantación
en virtud de la disposición contenida en el Artículo XII Sección 1c de los Estatutos del Sistema
Universitario Ana G. Méndez.
VIGENCIA

Esta orden ejecutiva que enmienda la política de ACUC entrará en vigor a la fecha de su firma y solo podrá ser derogada por otra orden ejecutiva

José F. Méndez, Dr.h.c.
Presidente

3/6/15
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Animal Care and Use Handbook

1. INTRODUCTION

The Ana G. Mendez University System (AGMUS) created an Animal Care and Use Program which complies with federal, state and local laws, standards and regulations, like; The Animal Welfare Regulations and Public Health Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare (OLAW). Therefore this Policies Prohibits the entrances, in all AGMUS facilities, of animals (vertebrate or invertebrate) and pets for exhibitions purposes, without the approval of the institution where the activities will be performed. Any research, training, or other activities involving the use of vertebrate animals must be evaluated and approved by the AGMUS Animal Care and Use Committee (ACUC). This approval must be obtained before any activity involving animals takes place.

2. REGULATIONS

2.1 Required Regulations

2.1.1 Animal Welfare Act and Regulations (AWAR)

Animal Welfare Act as Amended (7 USC, 2131-2156)
The complete Animal Welfare Act includes all amendments (1970, 1976, 1985, and 1990), following the 1966 enactment. This version is current through 1996 and can be found in United States Code, Title 7, Sections 2131 to 2156. (http://www.nal.usda.gov/awic/legislat/awa.htm)

Public Law 89-544 Act of August 24, 1966
Enacted August 24, 1966, Public Law 89-544 is what commonly is referred to as The Animal Welfare Act although that title is not mentioned within the law. It authorizes the Secretary of Agriculture to regulate transport, sale, and handling of dogs, cats, nonhuman primates, guinea pigs, hamsters, and rabbits intended to be used in research or "for other purposes." It requires licensing and inspection of dog and cat dealers and humane handling at auction sales. The complete amended act can be found in United States Code, Title 7, Sections 2131-2156. (http://www.nal.usda.gov/awic/legislat/pl89544.htm)

Public Law 91-579 Animal Welfare Act of 1970
Enacted December 24, 1970, Public Law 91-579 expands the list of animals covered by The Act to include all warm-blooded animals determined by the Secretary of Agriculture as being used or intended for use in experimentation or exhibition except horses not used in research and farm animals used in food and fiber research. Exhibitors are incorporated into the act and research facilities are defined. Retail pet stores, state and county fairs, rodeos, purebred dog and cat shows, and agricultural exhibitions are exempt from the Act. The Secretary is directed to develop regulations regarding recordkeeping and humane care and treatment of animals in or during commerce, exhibition,
experimentation, and transport. There is also mention of inspections, and appropriate anesthetics, analgesics, and tranquilizers. There are further regulations on dog and cat commerce. ([http://www.nal.usda.gov/awic/legislat/pl91579.htm](http://www.nal.usda.gov/awic/legislat/pl91579.htm))

**Public Law 94-279 Animal Welfare Act Amendments of 1976**
Enacted April 22, 1976, Public Law 94-279 is primarily refining previous regulations on animal transport and commerce. "Carrier" and "Intermediate Handler" are defined. Health certification prior to transport of sale is required and must be performed by a veterinarian. Licenses, method of payment, and penalties for violations are discussed. This amendment also introduces and defines "animal fighting ventures" to the Act. Animals used for hunting waterfowl, foxes, etc. are exempt. It is illegal to exhibit or transport via interstate or foreign commerce animals used in fighting ventures such as dogs or roosters. ([http://www.nal.usda.gov/awic/legislat/pl94279.htm](http://www.nal.usda.gov/awic/legislat/pl94279.htm))

**Public Law 99-198 Food Security Act of 1985, Subtitle F - Animal Welfare**
Also called "The Improved Standards for Laboratory Animals Act" and enacted December 23, 1985, this section clarifies what is meant by "humane care" by mentioning specifics such as sanitation, housing, and ventilation. It directs the Secretary of Agriculture to establish regulations to provide exercise for dogs and an adequate physical environment to promote the psychological well-being of nonhuman primates. It specifies that pain and distress must be minimized in experimental procedures and that alternatives to such procedures be considered by the principle investigator. It also defines practices that are considered to be painful. No animal can be used in more than one major operative experiment with recovery (exceptions are listed). The establishment of the Animal Care and Use Committee (ACUC) is introduced with a description of its roles, composition, and responsibilities to the Animal and Plant Health Inspection Service (APHIS). Also, included is the formation of an information service at the National Agricultural Library to assist those regulated by the act in prevention of unintended duplication of research, employee training, searching for ways to reduce or replace animal use, and to provide information on how to decrease pain and distress. The final section explains the penalties for release of trade secrets by regulators and the regulated community. ([http://www.nal.usda.gov/awic/legislat/pl99198.htm](http://www.nal.usda.gov/awic/legislat/pl99198.htm))

**Public Law 101-624 Food, Agriculture, Conservation, and Trade Act of 1990, Section 2503 - Protection of Pets**
Enacted November 28, 1990, and establishes a holding period for dogs and cats at shelters and other holding facilities before sale to dealers. It requires dealers to provide written certification regarding each animal's background to the recipient. Specific items included on the certificate are mechanisms of enforcement, injunctions, and penalties for violation. ([http://www.nal.usda.gov/awic/legislat/pl101624.htm](http://www.nal.usda.gov/awic/legislat/pl101624.htm))

**Code of Federal Regulations, Title 9, Chapter 1, Subchapter A - Animal Welfare.**
Available from: USDA, APHIS/Animal Care, 4700 River Rd., Unit 85, Riverdale, MD 20737-1234. The current version of the regulations developed by the U. S. Department of Agriculture specifies how to comply with the Animal Welfare Act and its amendments. The section is divided into 4 sub-sections: Definitions, Regulations, Standards, and Rules of Practice Governing Proceedings under the Animal Welfare Act. The Definitions
section describes exactly what is meant by terms used in the legislation. "Animal", for example, specifically excludes rats of the genus *Rattus* and mice of the genus *Mus* as well as birds used in research. The Regulations section includes subparts for licensing, registration, research facilities, attending veterinarians and adequate veterinary care, stolen animals, records, compliance with standards and holding periods, and miscellaneous topics such as confiscation and destruction of animals and access and inspection of records and property. The bulk of the subchapter is the third section, which provides standards for specific species or groups of species. Included are sections for cats and dogs, guinea pigs and hamsters, rabbits, nonhuman primates, marine mammals, and the general category of "other warm-blooded animals". Standards include those for facilities and operations, health and husbandry systems, and transportation. The final section sets forth the Rules of Practice applicable to adjudicating administrative proceedings under Section 19 of the Animal Welfare Act.


Often referred to as the "Preamble" to the Animal Welfare Act amendments of 1985, the explanations of the regulations are used to identify the intent of the regulations published in *Title 9, Code of Federal Regulations*. This issue contains final regulations developed to enact the 1985 amendments to the Animal Welfare Act covering the Definitions and Regulations sections. Extensive commentary is provided to respond to public comments about each of the proposed regulations. Comments and final regulations are provided in many areas including the structure and functions of the Institutional Animal Care and Use Committee; the principal investigator's consideration of alternatives that reduce, refine, or replace animal use; records; licensing; registration; stolen animals; and research facilities. ([http://www.nal.usda.gov/awic/legislat/awafin.htm](http://www.nal.usda.gov/awic/legislat/awafin.htm))


This issue contains final regulations developed to enact the 1985 amendments to the Animal Welfare Act covering the Standards section. Extensive commentary is provided to respond to public comments about each of the proposed regulations. Comments and final regulations are provided concerning exercise in dogs and psychological well-being in nonhuman primates. ([http://www.nal.usda.gov/awic/legislat/awadog.htm](http://www.nal.usda.gov/awic/legislat/awadog.htm))


The final rules implementing the 1990 amendment to the Animal Welfare Act and amending the animal welfare regulations by requiring pounds and shelters to hold and care for dogs and cats for at least 5 days (including one weekend day) before providing them to a dealer. Dealers must provide valid certification to anyone acquiring random source dogs and cats from them. Public comments and rationale for the regulatory decisions are discussed. This information updates *Title 9, Code of Federal Regulations, Subpart A, Parts 1 and 2*. ([http://www.nal.usda.gov/awic/legislat/cat1.htm](http://www.nal.usda.gov/awic/legislat/cat1.htm))
It revises several sentences in the original Final Rule.
(http://www.nal.usda.gov/awic/legislat/cat2.htm)

Animal Care Policies
The policy manual gives policies issued by APHIS/Animal Care that clarify the Animal Welfare Act Regulations. Among the topics covered are "Written Narrative for Alternatives to Painful Procedures", "Space and Exercise Requirements for Traveling Exhibitors", and "Annual Report for Research Facilities". Originally issued in April 1997, new policies may be added at any time and included in the manual.
(http://www.aphis.usda.gov/ac/polmanpdf.html)

2.1.2 Public Health Service (PHS) Policy

Passed by the U.S. Congress on November 20, 1985, this law provides the statutory mandate for the PHS Policy. It allows the Secretary, acting through the Director of NIH, to establish guidelines for the following:

- The proper care of animals to be used in biomedical and behavioral research.
- The proper treatment of animals while being used in such research.
- The organization and operation of animal care committees.

The Office of Laboratory Animal Welfare (OLAW, formerly Office for Protection from Research Risks, Division of Animal Welfare) at the National Institutes of Health, has responsibility for the general administration and coordination of the Policy on behalf of the PHS. (http://grants.nih.gov/grants/olaw/references/phspol.htm#1985)

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
The U.S. Principles were promulgated in 1985 by the Interagency Research Animal Committee and adopted by U.S. Government agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals. The Principles were incorporated into the 1986 PHS Policy and provide a framework for research conducted in accordance with the Policy.

The development of knowledge necessary for the improvement of the health and wellbeing of humans, as well as, other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually performs sponsor such procedures the responsible Institutional Official shall ensure that these principles are adhered to:
a. The transportation, care, and use of animals should be in accordance with the
Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws,
guidelines, and policies.*

b. Procedures involving animals should be designed and performed with due
consideration of their relevance to human or animal health, the advancement
of knowledge, or the good of society.

c. The animals selected for a procedure should be of an appropriate species and
quality and the minimum number required to obtain valid results. Methods
such as mathematical models, computer simulation, and in vitro biological
systems should be considered.

d. Proper use of animals, including the avoidance or minimization of discomfort,
distress, and pain when consistent with sound scientific practices, is
imperative. Unless the contrary is established, investigators should consider
that procedures that cause pain or distress in human beings may cause pain or
distress in other animals.

e. Procedures with animals that may cause more than momentary or slight pain
or distress should be performed with appropriate sedation, analgesia, or
anesthesia. Surgical or other painful procedures should not be performed on
anesthetized animals paralyzed by chemical agents.

f. Animals that would otherwise suffer severe or chronic pain or distress that
cannot be relieved should be painlessly killed at the end of the procedure or, if
appropriate, during the procedure.

g. The living conditions of animals should be appropriate for their species and
contribute to their health and comfort. Normally, the housing, feeding, and
care of all animals used for biomedical purposes must be directed by a
veterinarian or other scientist trained and experienced in the proper care,
handling, and use of the species being maintained or studied. In any case,
veterinary care shall be provided as indicated.

h. Investigators and other personnel shall be appropriately qualified and
experienced for conducting procedures on living animals. Adequate
arrangements shall be made for their in-service training, including the proper
and humane care and use of laboratory animals.

i. Where exceptions are required in relation to the provisions of these Principles,
the decisions should not rest with the investigators directly concerned but
should be made, with due regard to Principle II, by an appropriate review
group such as an animal care and use committee. Such exceptions should not
be made solely for the purposes of teaching or demonstration.
*For guidance throughout these Principles, refer to the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

The Public Health Service Policy on Humane Care and Use of Laboratory Animals
This PHS Policy can be found in Chapter 4206 of the NIH Manual and Chapter 1-43 of the PHS Manual. The NIH originally initiated the Policy in 1971. It was extended to all PHS activities January 1, 1979, and was revised in the spring of 1985 with implementation to be effective January 1, 1986. With the passage of the Health Research Extension Act of 1985 (PL-99-158), the policy was further revised and the Director of the NIH was required by law to establish specific guidelines. An additional revision was released in September 1986 reflecting the changes required by this Act.

Under the PHS policy, each institution using animals in PHS-sponsored projects must provide acceptable written assurance of its compliance with the Policy.

- **The Institutional Program** must include a list of every branch and major component of the institution to be covered under the assurance, the lines of authority for administering the program; the qualifications, authority and responsibility of the veterinarian(s), the membership of the ACUC and the procedures which they follow must be stated. The Occupational Health and Safety Program must be described for all those who have animal contact. A training or instruction program in the humane practices of animal care and use must be available to scientists, animal technicians and other personnel involved in animal care, treatment and use. The gross square footage, average daily census and annual usage of each animal facility must be listed.

- **The Institutional Status** must be stated as either:
  a. Category 1 - American Association for Accreditation of Laboratory Animal Care (AAALAC) accredited or ;
  b. Category 2 – Evaluated by AGMUS’ IACUC

- **The ACUC** must be appointed by the President and consist of at least five members; including a veterinarian with program responsibility, a practicing scientist, an individual whose expertise is in a non-scientific area and an individual who is not affiliated with the institution. This Committee must use the Guide to review the animal facilities and the institutional program for the humane care and use of animals at least once every six months and prepare reports of these evaluations for the responsible institutional official. The Committee must review and approve animal-related components of proposals and significant modifications made in ongoing activities involving the care and use of animals. The Committee is responsible for reviewing concerns involving the care and use of animals and making recommendations to the Institutional Official regarding any aspect of the animal program, the facilities, or the personnel training. The Committee is also authorized to suspend activity involving the care and use of animals as set forth in the PHS Policy.
In reviewing the animal care and use component of a proposal, the ACUC must confirm that the project will be conducted in accordance with the AWA and consistent with the recommendations in the Guide. In addition, all procedures are reviewed to assure that pain or distress will be minimized and that (when necessary) appropriate anesthetics, analgesics and tranquilizers will be used. The living conditions and medical care available must be appropriate for the species used, and personnel conducting the procedures must be appropriately trained and qualified. Methods of euthanasia should be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia.

- **The investigator** is responsible for completing a proposal in accordance with the recommendations in the PHS Policy and the instructions contained in the PHS 938 application packet. As of October 1988, the instructions for completing 398 can be found in two locations within the application package. On page 6, the research investigator's responsibilities for assuring the humane care and use of animals are clearly addressed. Detailed instructions for completing Section F of the Research Plan which describes the use of vertebrate animals can be found on page 21.

- **The institution** is responsible for maintaining all the necessary records to document compliance with the PHS Policy and for filing annual reports which detail any changes in the program and indicate the dates of the semi-annual inspections and programmatic reviews.

- **The PHS Policy** described above is intended to implement and supplement the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research and Training."

### 2.2 Voluntary Regulations

#### 2.2.1 Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC)

AAALAC International uses the revised Guide for the Care and Use of Laboratory Animals (*Guide*), NRC, 2011, as the basis for assessing and accrediting animal care and use programs. AAALAC has modified its position statements to reflect changes in the *Guide*. The following positions will be used by the Council on Accreditation to evaluate and accredit animal care and use programs.

Some statements are paraphrased or excerpted directly from the *Guide*; others are AAALAC International interpretations of the *Guide's* intent. The principles of the *Guide* are outcome-based and include professional judgment and performance standards. If a program deviates from the standards of the *Guide*, there must be compelling reasons with strong rationales for it to be acceptable.
a. **Laboratory animals**

All vertebrate animals used or to be used in research, teaching or testing at accreditable units are to be included and evaluated in relation to the principles set forth in the *Guide*. This includes traditional laboratory animals, farm animals, wildlife, and aquatic animals.

b. **Adequate veterinary care**

Veterinary care is an essential part of an animal care program. Veterinary care is the responsibility of a veterinarian who is certified or has training or experience in laboratory animal science and medicine in the species being held and used.

Some aspects of the veterinary care program can be conducted by qualified personnel other than a veterinarian; however, a mechanism of direct and frequent communication should be adopted so that timely and accurate information on problems in animal health, behavior, and well-being is conveyed to the attending veterinarian.

The veterinarian should also contribute to the establishment of appropriate policies and procedures for ancillary aspects of veterinary care, such as providing advice on humane animal use in light of scientific requirements; reviewing protocols and proposals with respect to veterinary care, animal husbandry, and animal welfare; monitoring occupational health, hazard containment, and zoonosis control programs; and oversight of animal nutrition, husbandry, and sanitation.

The veterinarian must provide guidance to investigators and all personnel involved in the care and use of animals to ensure appropriate handling, immobilization, sedation, analgesia, anesthesia, and euthanasia. The attending veterinarian must provide direction in the management of protocol-associated disease, disability, or other squeal; as well as oversight of surgery and postsurgical care.

c. **Occupational health & safety program**

An occupational health and safety program must be part of the overall animal care and use program. The basic elements of a program include hazard identification and risk assessment, personnel training and protection, written procedures and policies regarding hazard use and monitoring, and medical evaluation and preventive medicine. The extent and level of participation of personnel in the program should be based on the hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of the personnel; and on the history of occupational illness and injury in the particular workplace. A health history evaluation is advisable before work assignment to assess potential risks for individual employees. Periodic medical evaluations and
appropriate immunization schedules are advisable for some risk categories. Immunization of animal care personnel against tetanus is important.

In accordance with the Guide, assurance must be provided by an organization that all personnel at risk are appropriately considered under the occupational health and safety program.

d. Multiple major surgical procedures

Multiple major survival surgical procedures on a single animal are strongly discouraged. However, under certain circumstances they may be permitted when they are scientifically justified by the user and with the approval of the Animal Care and Use Committee. Multiple survival surgical procedures may be justified when they are related components of a research project and are deemed essential. Cost savings alone is not an adequate reason for performing multiple survival surgical procedures.

e. Survival surgery facilities

The AAALAC International position statement pertaining to survival surgical facilities has been withdrawn due to the detailed information provided in the Guide.

f. Farm Animals

AAALAC International uses the current edition of the Guide for the Care and Use of Laboratory Animals as its primary standard for evaluating animal care facilities and programs. The full range of programmatic criteria outlined in Sections I-III of the Guide are entirely applicable to farm animals, and in accredited facilities, the use of farm animals in research should be subject to the same general ethical considerations as the use of other animals in research.

However, uses of farm animals are often separated into biomedical uses and agricultural uses, and different criteria for evaluating standards of housing and care for animals of the same species may be appropriate. Decisions on categorizing research uses of farm animals and defining standards for their care and use should be based on user goals, protocols, and concern for animal well-being and should be made by the Institutional Animal Care and Use Committee.

For animals in an agricultural setting, AAALAC International takes the position that, in accredited facilities, the housing and care for farm animals should meet the standards that prevail on a high-quality, well-managed farm. The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (FASS 1999) is recognized by AAALAC International as a reference resource for individual farm animal species. Regardless of an investigator's research objectives or funding source, institutions are expected to provide oversight of all research animals and ensure that their pain and distress is minimized.
g. Cercopithecine herpesvirus 1, CHV1 (Herpesvirus-B)

In addition to using the revised Guide for the Care and Use of Laboratory Animals (Guide), as its primary document, AAALAC International also uses Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997, "Guidelines for the Prevention and Treatment of B-Virus Infections in Exposed Persons," Holmes, et al., Clinical Infectious Diseases 20:421-39, 1995, and the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 3rd Ed., 1993, as resources for assessing the appropriateness of measures to protect personnel and prevent transmission of CHV1.

Each AAALAC International accredited institution housing macaques must have a protection and prevention program for CHV1 as a part of its occupational health and safety program. All macaques should be presumed to be harboring CHV1 and handled accordingly.

The basic elements of the program include standard operating procedures and training for handling macaques and their tissues and dealing with potential exposures; risk assessment and education of all personnel having potential contact with macaques; the presence of supplies for immediate and appropriate patient first aid and animal specimen collection; maintenance of a bite, scratch, and incident log; the required use of appropriate protective equipment, including that necessary for hand and arm as well as for eyes and mucous membrane protection; and access to occupational health and safety staff and medical care staff knowledgeable of both exposures and acute disease.

2.2.2 Ana G. Méndez University System (AGMUS)

The Ana G. Méndez University System follows the regulations and guidelines of the Animal Welfare Act, the Public Health Service Policy, AAALAC and those outlined specifically for the University System. Specific guidelines are delineated in this manual.

2.3 Other applicable Laws and Regulations

2.3.1 Congressional Research Service (CRS) Report for Congress


2.3.2 Puerto Rico Laws

This law completely substitutes Law 67 of May 31, 1973, as amended as well as a number of other statutes dealing with animal protection and rights. This Act governs the provisions of the statutes that address specific cases and others are included to make it more comprehensive and rigorous. 


3. AGMUS ANIMAL CARE AND USE COMMITTEE

3.1 Authority

AGMUS has established an Animal Care and Use Committee (ACUC), which is qualified through the experience and expertise of its members to oversee the institutions’ animal program, facilities, and procedures. AGMUS acknowledges and accepts responsibility for the care and use of animals involved in all research and teaching activities within the University System, including the Universidad del Este, Universidad Metropolitana, Universidad del Turabo and all their University Centers. It has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide) NCR, 2011 and applicable laws and regulations.

The lines of authority and responsibility for administering the IACUC program and ensuring compliance with this Policy are:

The AGMUS President as Chief Executive Officer (CEO), has designated the Associate Vice President for Sponsored Programs and Compliance to serve as AGMUS Institutional Official (IO) to appoint the Animal Care and Use Committee (ACUC) and to assure compliance with the Public Health Service (PHS) Policy for the Humane Care and Use of Laboratory Animals (Policy), the AGMUS Assurance of Compliance with the PHS Policy, and all of its components to the terms of all applicable Animal Welfare Laws and Regulations.

The Office of Regulatory Compliance is part of the Associate Vice presidency for Sponsored Programs and Compliance. The Director of the Office of Regulatory Compliance reports to the IO. The Compliance Office is a system-wide office and works as a policy development office with assessment and coordination roles. It provides administrative and clerical support to all Regulatory Compliance Committees, including
the ACUC. Regulatory Compliance Committees are appointed with representation from all three universities, the AGMUS Central Administration, and the community. The Office provides clerical and administrative support to the ACUC and keeps copies of all ACUC documents (i.e., protocols, meeting minutes and letters of approval, renewal and/or non-approval, semi-annual program and facility reviews, reports to the IO and to OLAW).

AGMUS contracted an Attending Veterinarian (AV) to work with the ACUC and all animal related research investigations. The Attending Veterinarian has direct authority and responsibility to execute the Animal Care Program of adequate veterinary care at AGMUS and has access to all animals. There are open and direct lines of communication between the Attending Veterinarian and the AGMUS Institutional Official.

3.2 Membership of ACUC

The composition of the ACUC conforms to the overlapping, yet distinctive, requirements of the USDA and the PHS. The Committee is composed of at least five members appointed by the President of ANA G. MENDEZ UNIVERSITY SYSTEM or designee and includes the following:

- A Doctor of Veterinary Medicine either certified or with training and experience in laboratory animal science and medicine or in the use of the species at the institution.
- Alert one faculty member that is a non-scientist.
- At least one public member to represent the general community interests. Public member is not a laboratory animal user. The public member(s) is not affiliated with the institution and is not a member(s) of the immediate family of a person who is affiliated with the institution.
- There is at least one practicing scientist experienced in research involving animals representing each of the following: the animal lab, the farm and the field.
- Not more than three members are from the same administrative unit.
- One member is an institutional representative and serves as an ex officio non-voting member of the committee.

Each member is appointed for three years and may serve consecutive terms. The ACUC is a Permanent Regulatory Committee and reports directly to the Institutional Official.

3.3 Roles and Responsibilities

The ACUC is responsible for reviewing all research in which vertebrate animals serve as research subjects as well as the use of vertebrate animals in teaching. ACUC oversight covers all use of live vertebrate animals in research and teaching, whether in the laboratory or in the wild as a part of field research. Once approved, the ACUC maintains continuing oversight of the approved projects on an on-going basis and requires an
annual review and a complete resubmission on a triennial basis to both comply with the regulations as well as to vigilantly oversee the use of animals.

Not only is the ACUC responsible for ensuring that the protocols conform to acceptable standards and the regulations, it also ensures that the animal care program is in compliance. In this regard, the ACUC undertakes semi-annual program reviews and facilities inspections. This includes review and oversight over the activities of the Committee as well as a review of ACUC policies and procedures to ensure continued adherence to the highest standards of animal care and use. The results of these reviews are communicated to the Institutional Official for his/her consideration and, as necessary, action. Additionally, they form the basis for the required annual reporting to OLAW and USDA.

As part of its charge, the ACUC is expected to oversee the program on a continual basis and to report problems to the Institutional Official and, as necessary, to report unapproved variances from the standards of animal care and use promptly to the oversight agencies.

The AGMUS ACUC shall:

- Review at least once every six months the program for humane care and use of animals of all the institutions under AGMUS, using the Guide for the Care and Use of Laboratory Animals (Guide), and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use the Sample OLAW Program and Facility Review Checklist. The evaluation will include, but not necessarily be limited to, a review of the following:
  
  a. ACUC Membership and Functions;
  b. ACUC Records and Reporting Requirements;
  c. Husbandry and Veterinary Care (all aspects);
  d. Personnel Qualifications (Experience and Training); and
  e. Occupational Health and Safety.

  In addition, the evaluation will include a review of the Institution’s PHS Assurance.

- Inspect at least once every six months all of the AGMUS animal facilities (including satellite facilities) using the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use the Sample OLAW Program and Facility Review Checklist.

- Prepare reports of the ACUC evaluations as set forth in the PHS Policy at IV.B.3 and submit the reports to the Institutional Official. The ACUC
process for developing reports and submitting them to the Institutional Official is:

a. The ACUC members will convey their observations to the ACUC Chairperson who, in turn, will draft the reports using the sample format provided by OLAW for the Semiannual report to the Institutional Official.
b. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and this Policy, identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure.
c. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
d. If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.
e. The final reports will be signed by a majority of the ACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such.
f. The completed reports will be submitted to the Institutional Official. Copies of the reports will also be provided to the University Chancellor and the AGMUS Office of Regulatory Compliance.

- Review concerns involving the care and use of animals in AGMUS and its institutions;
- Make recommendations to the Institutional Official regarding any aspect of the AGMUS/Institutions animal program, facilities, or personnel training;
- Review and approve, require modifications in (to secure approval) or withhold approval of activities related to the care and use of animals;
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities;
- Be authorized to suspend an activity involving animals. If the ACUC suspends an activity involving animals, the Institutional Official, in consultation with the ACUC, will review the reasons for suspension, take appropriate corrective actions, and report that action to the NIH Office of Laboratory Animal Welfare (OLAW);
- Ensure that all personnel involved with animal care, treatment or use are provided with training on humane practice and the concept, availability and use of research, teaching or testing methods that replace, reduce, or refine the use of animals or animal distress;

- Ensure that all personnel involved with animal care, treatment or use are provided with training on occupational health and safety programs, their implementation and function in promoting employee well-being.

The Committee is dedicated to maintaining an open dialogue with investigators to achieve these goals, and it is the Committee's hope that investigators will see it as a resource for this purpose.

3.4 Structure and Organizational Chart

The AGMUS lines of authority and responsibility for ensuring compliance with the PHS Policy are depicted in the following organizational chart:
3.5 AGMUS-ACUC Contact Information

The Office of Regulatory Compliance maintains a website, compliance.suagm.edu, that lists a personnel directory and other contact information. You will also find ACUC information, forms and updates on compliance regulations. The Office is located in the Research Building of the AGMUS Central Administration (4th floor). The contact information is as follows:

Office of Regulatory Compliance:
Ana G. Méndez University System
Associate Vice-Presidency for Sponsored Programs

Physical address:
AGMUS Central Administration
Scientific Research Building, 4th Floor
Ave. Ana G. Méndez, State Road 176 km 0.3
San Juan, P.R. 00926

Postal address:
PO Box 21345
San Juan, P.R. 00928-1345

Telephone: 787-751-0178 ext. 7218, 7195, 7197
Fax: 787-751-9517, 787-759-6411
HOTLINE: 787-751-3120
4. ROLES AND RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS AND RESEARCH STAFF

4.1 Serving as a Principal Investigator on an Animal Protocol

While all members of a Research staff must be adequately trained and fully understand the proposed research project, it is the Principal Investigator (PI) who is responsible for the implementation of the protocol, for the actions of his/her research staff, and for ensuring that all policies of the ACUC and the Office of Regulatory Compliance are followed. The PI of an animal protocol is responsible for all aspects of the research contained therein. All correspondence regarding their protocols from the ACUC, including Committee deliberations and annual reviews, are directed to the PI because of his/her role. Because of these responsibilities and the importance of compliance to the institution, the PI on all submitted protocols must be a faculty member or associate of the Ana G. Mendez University System. Students may be included as qualified personnel or Co-PI's on a protocol if the principal investigator on that protocol assures their qualifications.

4.2 Principal Investigator Responsibilities

A PI is accountable for all aspects of the development and implementation of a protocol. PI’s responsibilities include but are not limited to:

- Development and submission of an ACUC protocol and ensure that no research is initiated until ACUC approval is obtained;
- Responding to the comments of the ACUC;
- Ensuring that all members of the Research staff are trained in the appropriate and relevant methods, species, and procedures as well as being extremely familiar with this handbook and the protocol;
- Conducting the protocol as approved;
- Submitting reports as required by the ACUC;
- Maintaining approval for the duration of the project; and
- Submitting any changes to the protocol for approval and initiating changes only after ACUC approval is received.

Investigators should note that failure to comply with federal, state, or local regulations on animal care and use or with the University System and ACUC policies and procedures may result in suspension of the approved protocol and notification sent, and a report to
the regulatory agencies and PI funding agencies. Equally important, as the result of such a violation to an individual PI, such failure can also jeopardize the AGMUS’s Animal Welfare Assurance on file with NIH and may lead to revocation of PHS research funding, as well as monetary fines and sanctions imposed by the USDA, as applies. Accordingly, it is important for all animal users to recognize that research with animals is a privilege, not a right and that all parts of the animal use community - PI's, research staff, the Office of Regulatory Compliance, ACUC and the Institutional Official - share the responsibility to protect the institution's ability to continue to conduct appropriate animal use.

4.3 Research staff

The Research staff listed in a protocol can be composed of co-investigators, fellows, technicians and students. The Research staff needs to be listed in the protocol and updated as needed.

While the PI is held responsible for all aspects of the conduct of animal care and use, each member of the Research staff bears a responsibility to ensure that animals are used in strict accordance with the protocol, institutional policy, and the ethical principles governing animal care and use. Therefore, each member of a Research staff must receive appropriate training, must understand the protocol and must be committed to the humane care and use of animals.

4.4 Types of Research and Protocol Requirement

4.4.1 Use of Live Vertebrate Animals

When live vertebrate animals are proposed for use in research and teaching, a full protocol must be submitted for review. A complete submission will include the basic protocol form as well as relevant appendices.

4.4.2 Use of Procured Tissue or Preserved Vertebrates

Research involving only the procurement of tissue from commercial sources or salvaged animals or the use of preserved vertebrates, obtained commercially or obtained from museums do not require ACUC review. However, it does require ACUC acknowledge. PI’s must complete and submit to the ACUC the necessary forms in order to obtain these acknowledge.

4.4.3 Special Considerations

4.4.3.1 Field Studies Involving Animals

Field research, including the capture and tagging of animals, the taking of blood samples, or other invasive or manipulative procedures requires the approval of the ACUC.
Investigators who plan to conduct field studies are required to submit an animal protocol to the ACUC for approval.

4.4.3.2 Collaborative Animal Use

Investigators with an appointment at AGMUS who plan to do collaborative animal research with individuals at other institutions are not required to submit an animal protocol if the protocol has already been approved at another institution for work to be completed at the other institution or an offsite location and funding is through the collaborative University unless funding flows through AGMUS. However, AGMUS requires a copy of the protocol and approval letter from the other institution before work commences. The ACUC would expect the PIs to collaborate only on projects where all of the basic ethical principles of animal care and use still apply.

4.4.3.3 Exempt Animal Use

Several categories of research are exempt from ACUC protocol review. These include but are not limited to field research involving only observation with no manipulation, research involving invertebrates, vertebrate eggs, tissues from colleagues who have protocols that are approved for the harvesting and sharing of such, and tissues obtained from commercial vendors or salvaged animals (found dead). Also exempt are commercially available "off-the-shelf" blood products, the use of enclosures that are not lethal or pain inducing, and ecological restoration solely for management purposes. To conduct research with these substances does not require the submission of a protocol to the ACUC. However, PIs must complete the required forms in order to comply with ACUC policies. PIs with questions regarding exemptions should contact the ACUC or the Office of Regulatory Compliance.

4.4.3.4 The Use of Animals in Teaching

The use of animals in teaching has come under closer scrutiny in recent years. The use of animals in teaching, demonstration or training is reviewed by the full ACUC at a convened meeting unless it falls under one of the previously described exemptions. The ACUC ensures that the use of animals is justified, that due consideration has been given to modeling or other means to communicate the same concepts and that, when appropriate, alternatives are available for students who are uncomfortable with the use of animal models.

4.4.3.5 Production Animals
In the event that a PI intends to research in areas requiring the use of production animals, he/she must receive previous written authorization from the corresponding Dean and Chancellor of their respective institution. Copy of the written authorization shall be remitted to ACUC records. Any related protocol, husbandry procedures and standard farm practices must be reviewed and approved by the ACUC at least every year.

4.5 New Principal Investigators

4.5.1 Before Arrival

New PI's that have research protocols approved at their previous appointment and will be continuing the research at the new appointment should contact the Office of Regulatory Compliance to initiate the process for protocol submission. Once a faculty appointment is confirmed, a new faculty member may submit protocols. Please note that even if the animal use received approval at another institution, it will require a completely new review by the ACUC of Ana G. Mendez University System. Moreover, as each institution has to interpret the regulations and standards governing animal care and use and each institution has its own culture, prior consultation with the ACUC and Office of Regulatory Compliance can be very helpful. This is particularly pertinent in situations where external grants will be transferred to Ana G. Mendez University System or where existing animals will be transferred, it is important to secure an approved protocol as soon as possible. Most agencies will not approve the transfer of an award if the institution cannot provide evidence of ACUC approval.

In summary, new PI's should:

a. Consult with the AGMUS Office of Regulatory Compliance regarding their animal needs, including space and species requirements;

b. Discuss transfer of awards and animals with the Dean of the corresponding unit and the Office of the Vice Chancellor of Sponsored Programs of the corresponding University;

c. Initiate preparation of an animal care and use protocol;

d. Review the Ana G. Mendez University System policies regarding animal care and use.

4.5.2 Upon Arrival

Upon arrival, new PI's and their investigative staffs should ensure that they are familiar with the practices and standards of Ana G. Mendez University System. This shall include:

a. Completing the required basic training module and all other training relevant to the facility or type of research;

b. Review this handbook and other relevant policy and procedure statements;
c. Make sure that all staff are listed on the protocol and that new staff are listed on the protocol under which they will be working. This should be done via an amendment before they begin working with animals;
d. Ensure that new staff have read and understand the protocol.

5. ACUC PROTOCOL PREPARATIONS AND REVIEW

The ACUC has responsibility for assuring that the research, teaching and testing programs involving animals at AGMUS provide for animal welfare and comply with regulations. To fulfill this responsibility, the ACUC reviews all animal research and testing procedures. **No animal experimentation or use is permitted at AGMUS or it's University Centers without written approval by the IACUC.** This requires all animal users at the University to complete the “ANIMAL PROTOCOL SUBMISSION FORM”. Investigators performing animal research, teaching, and testing can obtain this form the ACUC website at: compliance.suagm.edu or contact your Institution Office of Regulatory Compliance.

An animal use protocol is a written description of a planned research or teaching activity in sufficient detail to allow for a review of the proposed research activities by the ACUC. Research protocols submitted for ACUC review should be submitted on the most recent version of the ACUC protocol form and are asked to follow a particular outline, detailing just the information necessary for a proper ACUC review in clear and plain language. Incomplete protocols or protocols containing confusing or highly technical language will not be reviewed.

5.1 Preparing a Protocol for ACUC Review

5.1.1 The Animal Care and Use Protocol Approval Form

Forms, along with instructions for completing them, are available at the Office Regulatory Compliance of each respective institution, the AGMUS Office of Regulatory Compliance at the Central Administration or in the ACUC website at: compliance.suagm.edu

The most current forms are required to be submitted prior to review by the ACUC. Other forms of submission are not acceptable. The forms have been specifically designed to provide the information required by regulations and by the ACUC and AGMUS Office of Regulatory Compliance to conduct appropriate and complete review. The Animal Protocol Submission Form should be used for projects using live vertebrates.

5.1.2 What Should Be Addressed in a Protocol?

A protocol must be sufficiently detailed to permit the ACUC to evaluate the soundness of the procedures proposed and to determine appropriateness of the species, the proposed
number of animals, and that alternatives to using animals have been completely searched. The protocol form and its associated appendices will guide the PI to provide the necessary information. PI's should, however, ensure that they give full and detailed answers and complete all relevant supplemental forms. Sketchy answers or missing appendices will lengthen the review process.

The ACUC protocol review requires assessment of the following items:


**Activities** Must be in accord with USDA Regulations/PHS Policy.

5.1.2.1 **Pain Code Classifications**

The Ana G. Mendez University System-ACUC has established pain code to classify protocols according to the level of pain or unrelied distress involved. Investigators that complete a protocol must select the pain code that applies to the proposed work. If more than one classification applies, then an investigator should specify the percentage of animals in each.

The attending veterinarian must be involved in the planning. Use of paralytics without anesthesia is prohibited. Animals with chronic/severe unreliable pain will be painlessly euthanized.

The definitions of the pain code categories, as described in the protocol form, are as follows:

- **Classification A**: No pain, distress, or use of pain-killing drugs. (i.e., behavior studies, post-mortem tissue harvest; and routine procedures causing only transitory discomfort such as venipuncture, injections, ear tagging)

- **Classification B**: Pain/distress with appropriate analgesic/ anesthesia/ tranquilizers. Procedures involving accompanying pain or distress to the animals and for which the appropriate anesthetic (for surgery), analgesic (for inflammation or pain) or tranquilizing drugs are used.

- **Classification C**: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs. Examples:
  
  - Procedures performed correctly by trained personnel such as the administration of electrolyte/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice (dog cephalic, cat jugular) or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
- Euthanasia performed in accordance with the recommendations of the most recent AVMA Panel on Euthanasia, utilizing procedures that produce rapid unconsciousness and subsequent humane death.

- Manual restraint that is no longer that would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

If all or a percentage of animals will experience either category B or C, the PI must complete appropriate appendix to document that alternatives to painful or distressful procedures in animals has been considered. The regulations of the Animal Welfare Act (AWA) require that the principal investigator consider alternatives to procedures that may cause more than momentary (more than a simple injection) or slight pain or distress to animals. (PI's must provide a written narrative of the sources consulted to determine whether or not alternatives exist to procedures that cause pain or distress).

The USDA, which is charged with enforcing the AWA, has promulgated two policies (Policy #11 and Policy #12) that assist investigators in understanding how to comply with these regulations. Policy #11 provides the definition of what is considered a painful or distressful procedure, and provides examples of both. In general, any procedure that would be expected to cause more than slight or momentary and/or distress in a human to whom the procedure is applied is considered to be painful and/or distressful in animals. (http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy_1.pdf)

Policy #12 provides guidance in what the minimal written narrative should include. In general, this requires a narrative describing a specific literature search for alternatives, including databases searched, time period covered, key words used, and the date of the search. If alternatives are described but will not be used, the principal investigator must describe why these are not adequate for the project described. (http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy12.pdf)

- **Category D:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used. Examples:

  - Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, laparotomy or laparoscopy.
Blood collection by more invasive routes such as intracardiac or per orbital collection from species without a true orbital sinus such as rats and guinea pigs.

Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.

- **Category E:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery or test. Examples:

  - Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
  - Surgical and post surgical sequel from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
  - Negative conditioning via electric shocks that would cause pain in humans.
  - Chairing of nonhuman primates not conditioned to the procedure for the time period used.

**NOTE REGARDING CLASSIFICATION E:** An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drug must be provided on the USDA Classification E Form. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the Internet via USDA’s website. This form is available at: [compliance.suagm.edu](http://compliance.suagm.edu)

### 5.1.2.2 Justification of Non-Standard Methods of Euthanasia


The ACUC will evaluate each protocol on a case-by-case basis to determine whether the justification warrants approval of a non-standard method of euthanasia. Generally, animal care and use standards require that prior anesthesia or sedation be used in conjunction with a physical method of sacrifice (i.e., decapitation or cervical dislocation). In cases where a physical
method of sacrifice alone is proposed, the PI must provide a scientific justification, which should include research references, to explain why anesthesia or sedation cannot be used. The justification must include documentation of the alternatives considered and a description of the methods and sources used to determine that alternatives to the use of physical sacrifice alone were not acceptable or available.

5.1.2.3 Justifying the Number of Animals

The ACUC has a responsibility to ensure that the number of animals used is the minimum number that is sufficient to achieve the scientific or teaching aims. Toward that end, the protocol asks that PI's justify the number of requested animals in detail. Numbers should be based in a statistically valid power analysis or other specific justification. Investigators may not use more animals than the number approved by the ACUC. As part of its review process, the ACUC considers the appropriateness of the proposed animal numbers for the work proposed. PI's are expected to limit the number of animals to the smallest number, which allows meaningful conclusions to be drawn from the research. In cases such as field research where the PI cannot provide precise numbers or species lists, an appropriate justification should be made including estimates. The ACUC is responsible for ensuring that PI's do not use animals in excess of the numbers formally approved by the ACUC; the ACUC has asked the AGMUS Office of Regulatory Compliance to ensure that animals only be obtained up to the approved number.

In the event that during the conduct of the research, a PI determines that more animals than originally anticipated are required for the research, the PI is responsible for submitting an amendment requesting to increase the number of animals. This request should include not only the number of animals requested, but also a scientific justification for the increase. Such an amendment may be eligible for designated review, but depending upon the number of additional animals and the justification, the ACUC might determine that the amendment should be reviewed at a convened meeting.

5.1.2.4 Anesthesia

The protocol should outline in detail any proposed anesthesia (type of anesthesia, rate of administration, dosage, and timing). The attending veterinary can provide assistance to PI's in determining the most appropriate anesthetic regimen for the species and for the type of procedures. Anesthesia of laboratory animals is an art as well as a science. It is also a serious responsibility.

Significant animal pain and distress can result from poorly administered or inadequately monitored or inappropriate anesthesia. Only trained personnel should undertake animal anesthesia. The attending veterinarian is available,
not only for consultation in planning an anesthetic regimen, but also for training in administering anesthesia. Anesthesia must conform to the method approved by the ACUC in the specific protocol. It is the responsibility of the attending veterinarian and the PI that the use of anesthesia is formally documented in the corresponding records.

5.1.2.5 Analgesia

Analgesia is the relief or prevention of pain in the conscious patient. The attending veterinarian will assist in determining the need for analgesia and the appropriate analgesic regimen. The protocol should outline the proposed analgesia to be employed if pain is anticipated. It should be generally assumed that any procedure that would cause pain in humans would also cause pain in laboratory animals, and arrangements must be made to minimize pain. Unrelieved pain or distress is NOT acceptable except in circumstances where they have been scientifically justified and approved by the ACUC.

PI's should note that even after analgesic drugs have been administered, animals must be monitored closely for the adequacy and persistence of analgesia. Protocols should describe the plan for monitoring animals and should indicate who on the Research staff will be responsible for monitoring animals. Contact information is essential; this should be kept up to date. As with anesthetics, it is critical to document the administration of analgesia.

5.1.2.6 Surgery

Any proposed surgical procedures, both survival and non survival, must be fully described in the protocol. Non survival surgery is defined as a surgical procedure from which the animal does not awaken. Non survival surgery must meet applicable standards (e.g., clean instruments, surgeon appropriately garbed, in a suitable environment). Survival surgery, where the animal recovers from anesthesia, must follow strict standards for aseptic technique FOR ALL SPECIES and can only be conducted in a suitable environment approved for survival surgery.

It is essential that individuals performing surgical procedures be well trained to minimize animal pain and to ensure success of the procedure. Appropriate animal and surgeon preparation, aseptic technique, suitable environment, proper instruments, and knowledge of tissue handling and suturing are all essential components of good surgery. Individuals who need additional training in surgery should contact the ACUC attending veterinarian. The AGMUS Office of Regulatory Compliance also can provide training materials on the subject of aseptic surgical techniques.

Multiple major survival surgeries on a single animal are not permitted unless scientific justification is provided or approved by the ACUC.
5.1.2.7 Physical Restraint

Physical restraint may be a requirement of the research. However, such restraint must be made as painless as possible for the animals, should be of as short a duration as practicable and should utilize the most animal-friendly restraint system possible. The need to restrain animals should be fully described and justified in the protocol. Justification is particularly important if the restrain is of a long duration or the restraint mechanism itself is non-standard.

5.1.2.8 Food or Fluid Restrictions

Animal care and use standards require that animals receive food and drink consonant with their species and its natural needs. Any deviation from the standard diet of food or constant availability of water must be scientifically justified in the protocol and approved by the ACUC.

5.1.2.9 Housing/Health

Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise.

5.1.2.10 Duplication

PI must provide assurance that activities do not unnecessarily duplicate previous efforts.

5.1.2.11 Qualifications

Personnel must be appropriately qualified and trained.

5.1.2.12 Deviations proposed from Federal and ACUC Requirements

They must be justified for scientific reasons, in writing.

5.1.2.13 Documentation/Records

PI's and their staff bear much of the responsibility to prepare and maintain records of the many aspects of animal care and use that are required by regulation and practice. Such records must include: records of: animals received, animals used under each protocol, written narrative of methods/procedures performed on all animals, a rationale for any painful/distressful procedures anesthesia, analgesia, post-procedural care, euthanasia method and date, controlled substance use, training, breeding, basic animal care, and clinical care records. Consult the AGMUS Office of
Regulatory Compliance if you have any questions about the record keeping requirements for documentation of animal use.

5.1.3 Protocol Submission and Review Process

a. Download and complete the appropriate form(s). All forms and instructions for downloading and completing the forms are available on our website, compliance.suagm.edu or at your Institution’s Office of Compliance.

b. Complete, print and sign the forms.

c. The Animal Study Proposal Form is sent electronically by the Principal Investigator to the Office of Regulatory Compliance.

d. Although an electronic submission is required, it does not eliminate the need to provide the Office of Regulatory Compliance with a hard copy containing original signatures (blue ink signatures). This document will be filed in the Office for as long as indicated in the Federal guidelines.

e. The Animal Study Proposal Forms will be processed in the order that they are received at the Institution Office of Regulatory Compliance, unless qualifying under the expedited review criteria.

f. The Forms will be reviewed for accuracy and completeness, including all required training by individuals listed as working in the protocol.

g. The Institutional Compliance Coordinator will return the Animal Study Proposal Form to the PI if it’s incomplete or if there are questions that need to be addressed before appropriate submission to the ACUC.

h. A protocol number will be assigned by the Institutional Compliance Coordinator to each Study Proposal submitted to the ACUC for further and future reference.

i. The Institutional Compliance Coordinator will send the electronic version of the Animal Study Proposal Form to the ACUC Committee Members for review to decide whether the Study Proposal will be assigned as FCR or DRP.

j. ACUC members, including the non-university affiliated and non-scientific representatives have approximately three (3) working days after they receive the email from the Institutional Compliance Coordinator to complete and submit electronically the Determination Review Process Form (Appendix 1) to request a full committee review (FCR) to be conducted at the next convened meeting, otherwise the Designated Review Process (DRP) will be activated. Also ACUC Members must include in the Determination Review Process Form any comments and questions that may arise from the review.
• A study/proposal may not be disapproved outside of an ACUC convened meeting.

• A lack of response from a committee member within the three (3) working days is considered to be a tacit activation of the DRP.

• If any (one or more) ACUC members request for a full committee review (FCR), a convened meeting will be called.

k. After the determination of the review process is indicated (FCR/DRP), the Institutional Compliance Coordinator will refer the Study/proposal and all related documents to the Systemic Compliance Coordinator indicating the determined review process.

l. In an activation of the DRP, the Institutional Compliance Coordinator will send an electronic version of all documents submitted to the Systemic Compliance Coordinator who will coordinate with the ACUC Chairperson to designate three (3) ACUC members as reviewers. One primary reviewer and two (2) secondary reviewers will receive the protocol electronically from the Office of Regulatory Compliance. In addition, any ACUC member has the opportunity to volunteer to review the protocol. The Committee’s Veterinarian will always be included as one of the designated reviewers.

• The designated reviewers may: (1) approve the study/proposal as submitted; (2) request additional information from the PI to clarify and approve the study/proposal; or (3) request a full committee review at a convened meeting.

• A designated reviewer may not disapprove a study/proposal; the study/proposal must be referred for a Full Committee Review.

• The designated reviewers will have five (5) business days to review and submit their comments to the Office of Regulatory Compliance.

• The designated reviewers will submit their decision to the Office of Regulatory Compliance. Approval, comments or recommendations will be sent to the PI through the Office of Regulatory Compliance and will be relayed as a comment from the entire ACUC. An explanation of the Committee’s decision and/or any modifications required in order to secure approval are provided to the PI.

• All comments or correspondence with the PI should be made through the Office of Regulatory Compliance, including reply from the PI. Final approval will be notified to the PI.

m. Upon a full committee review (FCR) request, the submitted study/proposal will be assigned to the agenda of the next ACUC convened meeting. PHS Policy and
AWR’s are explicit that proposals reviewed by the Full Committee must receive the approval vote of the majority of the quorum present (50% + 1).

**Note:** No ACUC member can participate in the review of an activity in which that member has a conflicting interest except to provide information requested by the ACUC.

n. In the convened meeting the ACUC may determine different actions depending upon the findings of the committee: Approval, Modifications Required, Tabled and Not Approve. These actions are described in detailed in the ACUC handbook.

o. Any minority opinions will be appropriately noted in the meeting minutes.

p. As part of the review of a study/proposal the ACUC (representing a quorum) may decide to use the DRP subsequent to FCR when modifications are needed in order to secure approval.

q. The PI will be notified in writing with the actions and recommendations of the Committee via the Office of Regulatory Compliance. PHS Policy and AWR’s require the ACUC to notify investigators in writing of its decision to approve, require modifications, tabled or to not approve a study/proposal.

r. The PI has 30 working days to reply to the questions or recommendations raised by the ACUC at the convened meeting or by the DRP. Note that if no reply is received within 30 days, the ACUC will disapprove the study/proposal due to lack of response.

s. The Compliance Coordinator will send the Investigator’s responses and revised study/proposal to the ACUC members or Designated Reviewers members with copy to full ACUC Committee, as applies, for approval. This process will continue until all ACUC Full Committee members or the Designated Reviewers, as applies, have approved the protocol application and they have no more questions.

t. An approval letter is signed by the ACUC Chair or Co-Chair, as Acting Interim Chair for studies/proposal reviewed as FCR. When the DRP is activated the approval letter will be signed by the primary reviewer, designated by the ACUC Chair. These letters are addressed and delivered to the corresponding Principal Investigator (PI) through the Office of Regulatory Compliance.

**Remember that Animal Use conducted in the absence of an ACUC approval is a violation of the Ana G. Mendez University System Policies and commitment with the federal government.**

### 5.2 ACUC Review Determinations
For PHS Policy and the AWAR, IACUC’s either approve, require modifications to secure approval, or withhold approval of protocols (AWAR§2.31, c, 6; PHS Policy IV, B, 7). Also in accordance with AGMUS ACUC Policy the determination of Tabled protocol may apply.

**Approve**

The ACUC has determined that, for a particular animal use and teaching protocol, appropriate justification for animal use has been made, a search for acceptable alternatives to animal use has been demonstrated, and methods described are within standard and acceptable guidelines. The ACUC signifies its approval of a research protocol by issuing a letter to the Principal Investigator that the research protocol has been reviewed, approved, and may be conducted.

ACUC protocol approval is usually provided for a time period of three years as specified by PHS Policy IV, C, 1-IV, C 4. This policy requires *de novo* review of the protocol after three years. However, the AWAR (§2.31, d, 5) state that “the ACUC shall conduct continuing review of activities covered by this subchapter…no less than annually.” To aid compliance with both policies, it is recommended that investigators retain a copy of their protocol submission on their personal computer.

The Principal Investigator may enact research protocols approved under this procedure for a period not to exceed the approval period. The starting and ending dates of the approval period will be stated on the approval letter sent to the Principal Investigator. In certain cases the ACUC may require a shorter approval period and will require interim protocol status reports annually on the progress of the research and the status of the animals as a condition of approval. The exact period of approval, and any conditions, will be stated on the approval letter.

**Modifications required (securing approval)**

Protocols with a review status of withheld pending are most typically in need of one (or more) minor corrections or clarifications. *Conditional approval does not, however, mean that the study can be initiated.* The PI must first comply fully with all conditions arising from the ACUC’s review.

The Chairperson will write a letter to the Principal Investigator indicating that approval for the protocol is being pending certain minor revisions that must be made to the protocol. The letter will detail the items or questions requiring attention and a time frame for submitting revisions. The Principal Investigator will be invited to submit these revisions directly to the AGMUS Office of Regulatory Compliance. In certain cases the Chairperson might also elect to contact the Principal Investigator directly, to insure that the needed revisions are understood or to discuss ways the Principal Investigator might meet the requirements of the IACUC. If the Principal Investigator responds to these minor issues raised in the letter to the satisfaction of the Chairperson, the Chairperson, as designated reviewer, may approve the protocol as revised. If no revisions are made, or the
revisions are not satisfactory to the Chairperson, the protocol will be maintained as pending and will be scheduled for presentation and discussion at the next regular meeting of the ACUC committee.

**Tabled**

The ACUC may table a protocol pending receipt of additional substantive information or a significant revision of the protocol. This determination is used during the process of full committee review when the ACUC decides it is necessary for the whole committee to review the protocol again before further action can be taken. The protocol needs to go back to the next convened meeting.

**Not Approved**

The ACUC has determined that, for a particular research protocol, the risks outweigh the benefits to be gained by conducting that research. Approval may be withheld if any of the PHS Policy (IV, C, 1) or AWAR (§2.31, d, 1; §2.31, d, 2, e) criteria is met. Research protocols might also be denied because:

- The protocol is overly confusing or convoluted and not understood by the ACUC (e.g., poorly written or excessive technical language or jargon);
- Procedures described are not considered acceptable according to current standards and justification made was not sufficient to endorse deviation.

A protocol may also be administratively disapproved when a Principal Investigator has not responded to a request for additional information and/or modifications from the ACUC in a timely fashion (30 business days).

Ultimately the Ana G. Méndez University System and its institutions are responsible for the use of animals at its University Centers and Facilities. The disapproved proposals cannot be administratively approved by a higher authority. However, the opposite is not true; an ACUC approved proposal can be administratively disapproved by a higher authority due to financial, facility-related or other considerations. The ACUC will be duly advised of the determination in writing by the higher authority previous to the communication of the disapproval to the PI.

### 5.2.1 Other Determinations

**Termination**

The ACUC can terminate an approved protocol due to the following reasons:

1) Non-compliance issues
2) Failure to renew annually
3) Failure to complete the required training
For non-compliance issues, particularly those that involve animal welfare concerns, protocols can be terminated immediately. For failure to renew annually and failure to complete required training, the PI is given a 30 day notice prior to termination. PI will be notified of protocol termination in writing by electronic mail or written letter. The AGMUS Institutional Official and the Chancellor of the respective institution are notified in writing of all ACUC terminated protocols and will decide the deposition of study animals. Copy of the communication will also be sent to the PI’s immediate supervisor.

Withdraw

The PI can withdraw a protocol from the review process at any time by written communication to the ACUC Chair, with copy to the Compliance Director. The ACUC would then determine that the status of the protocol is withdrawn for the purposes of the official record.

5.3 Granting Agency Requirements and Protocol Submission

There are some sponsoring agencies that will not review research proposals involving animals unless formal notification of ACUC review and approval has been provided. Other agencies may review and score protocols but will withhold funding pending the receipt of ACUC approval. PI's are urged, therefore, to submit the ACUC protocol prior to the submission of a grant application, when possible. However, if a proposal is submitted to a funding agency before having submitted the protocol for ACUC review then the PI should immediately proceed to prepare and submit the protocol for review after having submitted the proposal, if this is allowable under the guidelines of the prospective funding entity.

It is critical that the protocol must reflect all proposed animal use detailed in the corresponding grant application. In the NIH application, for example, the Research Plan Section asks for specific information on the identification of the species and approximate number of animals to be used, rationale for the use of animals and appropriateness of the species and numbers, statements addressing steps to assure minimization of pain and distress, as well as, euthanasia methods. The answers to these specific points, as required by the grant application, should be fully reflected in the protocol.

The AGMUS will not process an award nor open an account until evidence of ACUC approval is provided for projects involving the use and handling of animals.

5.4 Questions and Appeals

Any PI may request an appointment with the ACUC Chairperson, or an opportunity to address the ACUC at a regular or special meeting, for any purpose related to the roles and responsibilities of the ACUC. The two most common reasons for such an appointment or hearing are to answer questions concerning protocols in development or research in progress, or to resolve difficulties related to the approval of a protocol. Concerns should be brought first to the Office of Regulatory Compliance and the Compliance Coordinator will contact the ACUC Chairperson. If resolution cannot be reached with the
Chairperson, the Principal Investigator may be scheduled to present his/her case before the ACUC at the next regular meeting or at a special meeting called by the Chairperson (if the situation warrants). The decision of the ACUC, however, is final and will be provided to the PI in writing.

5.5 A Note about Revisions/Changes to Proposed Protocols

Investigators should note that it is not uncommon for protocols received by the ACUC to require revisions. The goals of the process are to ensure humane care and use of animals, sufficient and accurate documentation in protocols, compliance with all applicable animal use regulations, and that the methods and practices proposed reflect the highest in current standards.

To facilitate the protocol development and review process, it is highly recommended that investigators work closely with the consulting veterinarian and the Office of Regulatory Compliance in advance of protocol submission. The protocol forms are also a useful guide to ensure that protocols are as complete as possible prior to submission. In addition, it is the ACUC's hope that the review process can facilitate research through education and by acting as a forum for discussion.

6. CHANGES TO APPROVED PROTOCOLS

6.1 Making Modifications (amendments) to Approved Protocols

For previously approved protocols, the AWA R (§2.31, d, 1) and PHS Policy (IV, C, 1, a-IV, C, 1) require that the ACUC review and approve, prior to initiation any amendments and modification to ongoing activities using animals. Modifications are submitted to the ACUC using the Animal Study Amendment Form available on the ACUC website compliance.suagm.edu.

The following table shows some examples of Protocol modifications and their category.

<table>
<thead>
<tr>
<th>Protocol Modification/ Amendments Categories</th>
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<tbody>
<tr>
<td>*Major Modification Request</td>
<td>Minor Modification Request</td>
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</table>
- Increase in animal numbers (>10% of original requested)
- Change or additional species (e.g. USDA-regulated species)
- Change of Principal Investigator
- Change in procedures (protocol change, distress, additional or new surgical procedures requiring anesthesia)
- Change in purpose or specific aim of study
- Addition of pain procedure (USDA pain categories)
- Addition of survival surgery
- Unanticipated marked increase in clinical signs than expected or proportion of animal deaths

| Increase in animal numbers (<10% of original requested). |
| Addition of another strain of the same animal species or change of animal gender. |
| Add/Change location (complete Section B). |
| Substitution or addition of personnel (student, technician or faculty collaborator. Complete Section B). |
| Need to repeat an experiment. |
| Additional sample collection times. |
| Additional minor surgery (complete Section B). |
| Additional non-invasive sampling. |
| Minor change in procedures (method of wound closure, change in appropriate antibiotic, changes in route of administration as long as it is not anticipated to induce more than momentary pain or distress). |

* If selected, you must complete ACUC_01 Animal Study Protocol Submission Form and resubmit the study proposal for ACUC review. Major modifications need to be review by the full ACUC.

Any changes to an ACUC protocol that present animal welfare issues not addressed in the original protocol will require the submission of a new protocol. The new protocol submission is required to address how the animal welfare issues will be mediated.

PHS Policy (IV, C, 2) and the AWAR (§2.31, d, 2) require the same review procedures for proposed changes in ongoing activities (protocols) as they do to new activities.

a. An ACUC Administrative Modification represents a minor modification (amendment) as described in the table above. All ACUC members must have the opportunity to evaluate proposed amendments. If a proposed amendment qualifies for Administrative Modification, the DRP will be activated as indicated in section 5.1.3 (l) of this handbook.

b. **If the proposed modification is major or significant, it needs to be reviewed by the ACUC in a FCR at a convened meeting** as described in section 5.1.3 (m) of this handbook. Also a minor modification can be reviewed by the FCR if one of the ACUC members requests the modification to be reviewed at the next convened meeting.
Note: It is the responsibility of the principal investigator to clearly explain, on the Animal Study Amendment Form, why the modification is being requested and how it relates to the original specific aims of the previously approved protocol.

7. LENGTH OF APPROVAL, ANNUAL REVIEW REQUIREMENTS AND TRIENNIAL RESUBMISSION OF PROTOCOLS

7.1 Length of Approval

The length of a protocol approval will be determined by the ACUC. Although an approved protocol is limited to no more than three years, as indicated in the PHS Policy, each protocol must be updated and reviewed "not less than annually" as required by AWAR. When proposal funding periods do not correspond with ACUC approval periods, PI's are urged to renew protocols in advance (at least 45 days) of the triennial (3yr.) anniversary date to avoid inconveniences with the funding agency and the ACUC.

Protocols may be approved for renewal up to a maximum of three consecutive years from the original date of approval, in periods not to exceed one year. Shorter approval periods may be required depending on the circumstances of the research, reporting requirements to internal or outside agencies, and the risks to the animals.

7.2 Annual Protocol Renewal & Status Reports

The AGMUS ACUC has instituted an annual study renewal process to comply with the Animal Welfare Act Regulations (§2.31, d. 5). Failure to complete the annual review process will result in the suspension of animal ordering privileges on that protocol. Continued failure to comply may result in the suspension of the protocol itself. If this occurs, the research approved under the protocol MUST cease, the animals must be either euthanized or transferred to another approved protocol.

The Principal Investigator will be contacted on a yearly basis for renewal. Principal Investigators will be sent a letter from the AGMUS Office of Regulatory Compliance requesting an Animal Study Renewal Form which the PI is required to complete, sign and return to said Office before (45 days) prior the annual date of the protocol. The Animal Study Renewal Form can be accessed in our website at compliance.suagm.edu.

Please note: Inadequate or incomplete responses will result in follow-up communication from the ACUC. The ACUC will terminate protocols that an investigator has failed to update in a timely and appropriate manner through the annual review process by the expiration date.

The ACUC chairperson is responsible for the review and approval of fully completed and signed Animal Study Renewal Forms, the AGMUS Office of Regulatory Compliance will provide the protocol with an updated approval date. The renewal date will be
effective for one year and always on the anniversary date of the original approval date, unless there is cause for interim review.

Changes of substance indicated on the annual review form could require an amendment to be submitted. Depending upon the content of the amendment, the request will be reviewed by the ACUC chairperson or referred by the Chairperson to a full committee process.

7.3 Triennial Resubmission

Each protocol must be resubmitted in full (de novo) every three years and reviewed by the ACUC. This ACUC policy is designed to recognize and comply with PHS policy, as well as, ACUC and other animal care/use standards and policies that are ever evolving, in order to allow protocols to meet any new standards. It also recognizes that science is constantly changing and it may be necessary to adapt the protocol's hypothesis and scientific rationale, as well as, its procedures to the changes in science.

Resubmissions are intended to replace, in full, all previous submissions of a given protocol, as well as, any amendments to the protocol. The resubmission should incorporate all of the approved amendments, any additional proposed changes and must include updated evidence of having gone through a scientific merit review, whether by an external funding agency or by the investigator's primary department or School.

The resubmission must be complete enough to stand on its own without reference to the previously approved protocol. Existing protocols that are not approved through the triennial resubmission process on or before their anniversary date will be expired. Once expired, the research must cease. Any animals remaining in Ana G. Mendez University System facilities must be transferred to another active protocol or be euthanized, unless otherwise covered under an ACUC approved Standards of Operations Procedure of an animal facility. Accordingly, PI's are urged to respond promptly (45 days prior expiration date) to requests for three year resubmissions.

8. ANIMAL FACILITIES AND HUSBANDRY ISSUES

8.1 AGMUS Animal Facilities/Laboratories

The AGMUS institutions may have a diversity of animal projects and/or studies. Each must be duly reviewed and approved by the ACUC for the use and care of vertebrate animals BEFORE being used for any educational or research purposes at the institution.

8.1.1 Access

Access to Animal Resource Center (ARC) facilities is strictly limited to individuals on an approved ACUC protocol who have had the appropriate orientation including the basic training module in the care and use of animals and facility-specific orientation. For more
information on Animal Care and Use Certification contact the AGMUS Office of Regulatory Compliance. After a protocol has been approved and training has been completed, the key or personal electronic access code at any pertinent animal facility or laboratory at an AGMUS institution may be obtained by presenting the approved protocol to the corresponding authorities of the institution at which the facilities are located.

When a protocol expires, the PI will be sent a letter stating that the key to the facility must be returned within 30 days, or that their personal electronic access code will be deactivated within the same period, as applicable. Individuals who do not have approval to enter the facilities should not be allowed to follow or accompany an individual that has approval to enter the facilities. This could result in a suspension of an individual's ability to enter the facilities. As we strive to maintain healthy, clean and safe animals, it is important that all individuals ensure that only trained and approved individuals are allowed to enter facilities.

ACUC members and federal and state officials, as determined by law or regulations, are authorized to visit the facilities for the inspection.

8.1.2 Visitors

Visitors (anyone not listed on an approved protocol) are not allowed in the Animal Resource Center (ARC). Exceptions may be allowed by special permission from the ACUC Chairperson in consultation with the Chancellor or Principal Investigator.

8.1.3 Centralized Purchase of Animals/Animal Products

Animals may only be purchased, procured or received through the central purchasing system established by the AGMUS Purchasing Office. This process is used for all animal and related animal products (i.e., cages, food, and bedding). This includes animals that are not purchased (e.g., those transferred from another University) but which are being brought into the University. This system is a critical component of the University's compliance program, ensuring that all animals are procured under an approved protocol and the number of animals being bred or procured is consistent with the total number of animals approved by the ACUC.

Through the central process, PI's can be sure that animals are housed appropriately on arrival, and that new animals do not endanger the health of existing colonies. For certain species, the program also ensures that as animals are received at the University, they are included in the institution's infection control program which has been designed to eliminate, to the extent possible, such animal infections as pinworm, mouse hepatitis virus, etc.

To place an order, PI's or their staff should contact the AGMUS Purchasing Office, ordering information must include the source, strain, and housing site, along with the appropriate account and protocol number. Before placing an order, the Purchasing Office personnel ensures that the PI has an approved protocol, which the species being procured has been approved and the proposed numbers are within the number of animals. In addition, requests for special feed, bedding, or equipment must be placed by the Principal
investigator procurement services of the Purchasing Office such requests will be checked for consistency with an approved protocol.

Upon arrival animals will be inspected, quarantined, if necessary, for an appropriate time, and housed in appropriate caging as soon as possible after receipt. The length of the quarantine depends upon the source (approved or unapproved vendor), the species of animal and the health status (known/unknown) of the animals. If the length of the quarantine presents special scientific issues, PI's should contact the ACUC Chairperson prior to ordering animals.

8.1.4 Housing Standards

Appropriate housing is a key concern in regards to animal welfare. The NRC *Guide to the Care and Use of Laboratory Animals* and the USDA regulations provide guidelines regarding housing issues, including cage size, cage type and numbers of animals per cage (density). Any variance to the standards for animal housing specified in the *Guide* or regulations must be specifically reviewed and approved by the ACUC.

8.1.4.1 Overcrowded Cages

As outlined in the *Guide*, section on Housing Standards, there are guidelines regarding the allowable number of animals per cage (density). Any variance to these standards must be approved by the ACUC. The ACUC will request full justification from the PI on scientific grounds and documentation that under the requested variance the animals' environment will meet the standards (e.g., fecal build-up, ammonia levels, etc.) for humane care.

When overcrowding has not been approved in advance occurs and is noted by the ACUC or the Office of Regulatory Compliance, the PI will be contacted and an "overcrowded" cage notification will be placed in the appropriate cages. It is the PI's responsibility to resolve the overcrowding problem. In instances of habitual overcrowding by the same PI, the ACUC will be notified and will contact the investigator. Blatant disregard for the standards of density will be handled in the same way as other instances of non-compliance (retraining requirements, voluntary suspension of activity, loss of animal use privileges, suspension of protocol and notification to OLAW and sponsor).

8.1.5 Animal Care

8.1.5.1 ACUC Standard Animal Care

Standard animal care varies by facility and species. Investigators should consult the *Guide* to understand the usual care, which will be provided,
including such elements as food, housing density, and cage change frequency.

8.1.5.2 Documenting Animal Care

The requirement for documentation applies whether the laboratory staff or PI performs the care. Check-off sheets are posted in each animal room by which the staff of PI records the frequency and completion of animal care duties. APHIS/AC Policy 3 specifies that records must be legible and include: animal identity, description of illness, injury, distress, and/or behavioral abnormalities, and the resolution of any noted problem, dates, details, and results of medically related observations, treatments and treatment plans, among others. Investigators are invited to review these records and to consult the Veterinarian when animal care questions arise.

8.1.6 Ensuring Animal Health

8.1.6.1 Health Maintenance

Animals must be observed daily by animal care staff or, in certain approved cases, by research staff. In all cases, observations should include checking for signs of pain or distress. Unanticipated pain or distress (e.g., due to illness or injury not described in an approved animal use protocol) must be reported to the ACUC through the Office of Regulatory Compliance. According to federal regulations, the researcher is responsible for consulting with the attending veterinarian or designee in the planning of procedures that may cause more than momentary or slight pain or distress in animals. At Ana G. Mendez University System, this is included in the protocol review process for the evaluation of the consulting Veterinarian. Pain and distress, which is anticipated in the course of an experimental manipulation, surgical procedure, teaching or testing exercise, must be described in an animal use protocol. Drugs for alleviating pain must be provided unless approval for withholding such agents has been granted via an animal use protocol. Animals may exhibit pain and distress in ways not obvious to the casual observer. Research staff should report immediately any unusual behavior in research animals to animal care personnel or to the Office of Regulatory Compliance or the consulting Veterinarian.

8.1.6.2 Veterinary Care: Health Problems

Investigators who observe abnormalities should report these to the ACUC. Room monitoring sheets outside each animal room record health problems or deaths. Investigators should work closely with the Veterinarian to
determine the cause and most appropriate treatment for health problems that arise.

Any unusual illness, injury and death of laboratory animals must be reported immediately to the ACUC through the Office of regulatory Compliance. This policy applies to all teaching and/or research vertebrate animals that are housed at Ana G. Mendez University System facilities.

With the exception of first aid or emergency life-support provided by appropriately trained personnel, animals should not be treated for illness or injury prior to consultation with the consulting veterinarian or emergency veterinarian.

8.2 On-Campus Satellite Animal Facilities

The regulations require that any facility in which animals are housed must comply in full with the requirements of the Guide for the Care and Use of Laboratory Animals. These requirements include issues of cage size, HVAC, illumination, etc. It is difficult for research laboratories to achieve these standards. Therefore, the ACUC and the Office of Regulatory Compliance rarely approve the use of rooms outside of the Animal Resource Center (ARC) for housing research animals.

To request ACUC approval to use a facility outside the ARC, the PI should complete the necessary forms available at the ACUC website, contact the Office of Regulatory Compliance and fully explain why the ARC facilities cannot be used. In addition, the route of animal transport from the ARC to laboratory areas must also be detailed in the ACUC Form and will be subject to the review of the ACUC. As part of its review, if the room has not been approved previously by the ACUC for animal use, the ACUC will inspect the room for compliance with regulations. The ACUC will notify the investigator by letter if the room use request has been approved. Changes in the usage of rooms or location of rooms used for animal work must be approved by the Office of Regulatory Compliance and the ACUC prior to initiation of those changes. Any external sites where live animals are housed or survival surgery on animals is performed will be inspected by the ACUC on a semi-annual basis.

8.3 Animal Transport

While the majority of animals remain in the ARC facilities, there are some types of research that necessitate that the animals are moved from the facilities to individual laboratories. Such a requirement must be justified on scientific grounds and is subject to the prior approval of the ACUC. In approving the transport of animals from the ARC facilities to a laboratory, the ACUC will consider issues of employee health, safety and sensitivity. Every effort must be made to lessen the opportunity for cross-contamination between humans and animals, and to avoid exposure to individuals who may be sensitive to the use of animals in research and teaching.
The PI also needs to describe the animal transport procedure to be used within the AGMUS institution (including route and elevator(s) to be utilized). Transportation of animals must comply with all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of town, the PI needs to describe efforts to comply with USDA regulations. If animals will be transported between AGMUS facilities, the description of the methods and containment that will be used must be fully explained in order to obtain ACUC approval.

8.4 Facilities Inspections

8.4.1 Inspections by the ACUC

To ensure that the animal program continues to reflect the highest standards of animal care and use and in compliance with regulatory requirements, the ACUC performs semi-annual facilities inspections as part of its semi-annual program review. The ACUC inspects the ARC facilities, as well as all satellite labs where animals are maintained for periods longer than 12 hours or where survival surgery is performed. Inspection teams consist of at least three members of the ACUC usually including the consulting veterinarian. The team evaluates each area for compliance using the Animal Welfare Regulations and the Guide for the Care and Use of Laboratory Animals to ensure conditions are in accordance with the humane care of animals and for adherence to the approved protocol.

Inspection teams review each area for issues such as general cleanliness, proper storage of food, proper disposal of animal waste, lack of clutter, and conditions that pose a threat to the well being of animals (e.g., storage of flammable or toxic substances next to animal cages). The teams also determine whether surgical procedures are performed using proper aseptic techniques (e.g., use of gloves, masks, sterile instruments, isolated area for surgery) as required, whether the areas where the animals are maintained satisfy the criteria for sanitation and impervious surfaces, and whether animals are being housed outside of approved housing facilities.

In addition to inspecting the facilities, inspection teams may question the PI and members of the research staff about the standards of animal care and use, the ethics governing animal use, the specific procedures being performed (e.g., means of euthanasia, pain/distress experienced by the animals, or the training and qualifications of persons handling the animals) and the content of the approved protocol. PI's are reminded that all members of the research staff should have read and be familiar with the protocol and copies should be readily available as reference tools in the laboratory.

For each room, the inspection team completes an inspection form and indicates any problems that the team identified. For each item, the ACUC agrees on a timeframe for its resolution. The results of the semi-annual inspections and program evaluations are summarized in a report to the Institutional Official for Research Compliance. Questions regarding the inspection process may be addressed to either the ACUC or the Office of Regulatory Compliance.
8.4.2 Inspections by the USDA

Although OLAW will conduct on-site audits for cause, the United States Department of Agriculture (USDA) conducts inspections on a regular, usually annual, basis. These inspections involve a thorough review of all aspects of an institution's animal care and use program. In addition to facilities inspection, the inspector may examine the Office of Regulatory Compliance and ACUC policies for compliance with all applicable regulations. The inspector may review the ACUC minutes for the preceding year and will identify protocols involving USDA covered species for in depth review. During the site visits, which are unannounced, the inspector interviews a number of key individuals responsible for administering the program.

8.5 Survival Surgery Facility

A survival surgical procedure is defined by the ACUC as any surgery where the animal is allowed to regain consciousness or where the animal is under anesthesia over eight hours. There are a variety of special concerns that survival surgery raises and particular requirements regarding facilities, training, aseptic techniques, analgesia and anesthesia.

8.5.1 Survival Surgery and Aseptic Techniques

The NRC Guide for the Care and Use of Laboratory Animals and the regulations outline stringent standards for the physical design and management of animal surgical facilities and their support areas. These areas are routinely inspected and approved by regulatory agencies and the ACUC. Survival surgeries on USDA covered species may only be done in ACUC approved facilities. All survival surgeries including those done in rodents must employ aseptic techniques. All details of aseptic methods must be itemized in the protocol.

8.6 Disposal of Animal Remains (Carcass Disposal)

Animal facilities must have approved policies and Standard Operating Procedures (SOP’s) approved by the ACUC for carcass disposal and the PI needs to refer to those. If you are deviating from the SOP's, explain in the ACUC protocol submission form what will be done and justify. For help in determining acceptable plans for identifying and bagging radioactive or biohazardous carcasses, PI's can contact the Office of Regulatory Compliance and the Institutional Biosafety Committee (IBC). In addition to the ACUC, the Institutional Biosafety Committee (IBC) will also review plans as described in the protocol for disposing of carcasses containing biohazardous materials.

It is critical that PI's review the procedures for carcass disposal, and especially carcasses with radioactive or biohazardous materials, with their research staff. Any violations of this procedure will be considered as potential serious non-compliance and will be fully
investigated by the ACUC. It is possible that such a violation would require the institution to report to OLAW or other oversight agencies and could result in suspension of animal protocols of the investigator/instructor involved.

9. PROCESS FOR RESEARCH

9.1 Process for Investigating Harm and/or Possible Non-Compliance

The ACUC has the responsibility of overseeing the protection of animals used in research. The ACUC insures this responsibility by investigating complaints of harm due to a research process, or Principal Investigators (or co-investigators) not following their approved research protocols.

Principal Investigators are required to follow the research protocols they have submitted to and approved by the ACUC. Principal Investigators are also required to promptly report to the ACUC any harm experienced by animals.

Initial reports of harm or possible non-compliance should be brought to the attention of the ACUC Chairperson, any ACUC member, or the Office of Regulatory Compliance Coordinator. The Chairperson, in consultation with the Compliance Director, the Compliance Coordinator, and any other ACUC members as might be required, conducts the initial research. The purpose of the initial research is to, as quickly as possible, determine two points. First, does the assertion of harm or non-compliance have any merit (is it worth further investigation)? Second, are animals at risk if the research study is allowed to continue?

To answer these questions the Chairperson may interview the Principal Investigator and co-investigators and others, examine research records requested from the investigators, and also personally inspect research facilities and equipment. This initial research should take place as quickly as possible, typically within a few days of receiving the initial information. If no harm or possible non-compliance is uncovered no further action is necessary. The Office of Regulatory Compliance or the ACUC will, however, temporarily suspend the animal use if this initial research uncovers information supportive of harm or non-compliance. If should this occurs, the Chairperson will notify, verbally and in writing, the Principal Investigator, their department Chairperson or unit supervisor, the ACUC Chair and the Institutional Compliance Coordinator that the research has been temporarily suspended.

9.1.1 Suspension

Suspension of research activities, during which no research involving animals may be conducted, may be required by the ACUC. The Full ACUC, at a convened meeting, may suspend the ACUC’s approval for a protocol if it is believed that harm has occurred
and/or is likely to occur (or re-occur) if the research is allowed to continue. A suspension automatically begins a research of the circumstances resulting in the suspension.

Such a research will comply with ACUC and AGMUS policies and procedures for investigating research misconduct. Complaints of harm or possible non-compliance that the Chairperson has found to have merit, regardless of whether a research protocol has been temporarily suspended, will be brought by the Chairperson to a special meeting of the ACUC within two weeks of the Chairperson’s determination. At this meeting the ACUC will be presented with whatever facts have been collected thus far. The Principal Investigator, co-investigators, and any others with relevant information will be invited to present information to the committee. The ACUC will then decide if further research is needed or if sufficient information is available to determine whether a harm or non-compliance has occurred. The ACUC will also decide if the research protocol should be continued as originally approved, reinstated (if temporarily suspended), suspended pending a further research by the ACUC or a revision by the Principal Investigator, or terminated (the ACUC withdraws approval for the study).

9.1.2 Non-Compliance

Occurs when a Principal Investigator, or other researchers under the direction of the Principal Investigator, either: (a) engage in research activities other than those approved in the original (or modified) research protocol; (b) continue to engage in approved research protocol activities beyond the time period specified in the approval period, or; (c) engage in any activities involving animals without a protocol previously approved by the ACUC. Instances of non-compliance will follow with ACUC and AGMUS policies and procedures for investigating research misconduct. All instances of non-compliance will be reported by the ACUC to the Institutional Official for Research Compliance. Some instances might require reporting to other local, state, or federal departments or agencies.

9.1.3 Termination

Termination of research activities results when a prior approval from the ACUC is withdrawn due to substantiated instances of harm (or the potential for previously unrecognized harm) to animals and/or confirmed circumstances of non-compliance. If harm or non-compliance is determined, the ACUC will recommend sanctions for the researcher that they deem appropriate. These recommendations will be submitted in writing, along with a summary of the incident of harm or non-compliance, and ACUC’s subsequent research, to the Institutional Official for Research Compliance from the ACUC. The Institutional Official, if agreed, will articulate these sanctions, to the PI in writing.

Certain agencies, both within and outside AGMUS, require notification whenever harm or an issue of non-compliance in research is determined. The ACUC Chairperson and the Office of Regulatory Compliance ensure that these notifications are made in a timely
fashion to the appropriate agencies by the Institutional Official. Principal Investigators must be aware that a suspension or termination of ACUC approval can result in the freezing of internal or extramural grant accounts, the return of equipment or other resources, and further investigation by other entities.

When the ACUC withdraws its approval for a research project the project is considered terminated and no further research involving animals may be undertaken. A new protocol will need to be submitted, reviewed, and approved.

9.2 Reporting Concerns about Animal Care and Use

The system of regulatory oversight and compliance is founded upon a trust between the regulatory agencies, the Institutional Official, the ACUC, the Office of Regulatory Compliance, and the PI and his/her research staff.

The entire community bears a responsibility to uphold the ethical and regulatory requirements associated with animal use. In this regard, it is critically important that the institution and its community demonstrate ability to policy itself.

Consistent with its commitment to humane animal care and use, AGMUS encourages anyone who perceives a problem with the way in which animals are housed, handled, or used in research or teaching to report their concerns. This includes the use of animals in ways that differ from the approved protocol. Such matters may be discussed with the Office of Regulatory Compliance. Reports may be made anonymously. The ACUC will investigate complaints and take appropriate actions as necessary to alleviate the problem. Animal-related emergencies should be reported immediately to the Office of Regulatory Compliance Hotline 787-751-3120.

10. TRAINING IN THE CARE AND USE OF ANIMALS

Training should be thorough and documented prior to the trainee being allowed to work with animals unsupervised.

10.1 Mandatory Investigative Staff Training

Research staff must be adequately trained in animal handling, the procedures specified in the protocol research procedures, anesthesia, surgery, and euthanasia. No member of a research staff may participate in research without fulfilling certain educational and training requirements. The exact requirements depend upon the individual's previous training and experience - requirements vary with the individual based not only on prior experience, but also on the animal species and types of procedures to be used, housing or other special requirements. All those listed as members of a research staff (e.g., the Principal Investigator, co-investigator(s), technicians, students, post-docs, among others that will be involved in working with animals), must complete the following:
- Review the Ana G. Mendez University System Animal Care and Use Policy and Handbook.

- Complete the AGMUS Animal Care and Use Certification training modules no less than every three (3) years. This certification can be completed in www.citiprogram.org

- Protocol-specific training: Additional training may be needed for the use of certain facilities or for certain species. These additional training sessions are also available at www.citiprogram.org as optional modules. Some procedures, such as the use of hazardous chemicals, biohazards, or radiation will also require specific additional training. Such training must also be documented, and periodic retraining may be needed. PI's are responsible for this training with the support of the Office of Regulatory Compliance and the ACUC. These might include: training on barriers or biohazard training, or safety training for specific biohazardous agents, radiation or hazardous chemicals.

This requirement is waived for individuals working exclusively at another institution, but collaborating with a principal investigator at Ana G. Mendez University System. If an individual, whether PI or a member of the research staff fails to adhere to the protocol or to institutional expectations regarding animal care and use, the ACUC can determine that he/she should not be allowed to work further with animals.

10.2 Documenting Training

The Office of Regulatory Compliance maintains a database by which it retains documentation that individuals have completed the training requirements. The ACUC also recommends that investigators keep curriculum vitae and resumes of staff working with animals on file to document applicable experience.

10.3 ACUC Member Training

All members of the ACUC receive training upon joining the committee. They are expected to attend a training session offered by the Office of Regulatory Compliance and ACUC. In addition, they are expected to familiarize themselves with the regulations, with ACUC and regulatory compliance policies and procedures by reading relevant materials, or completing the ACUC training module in www.citiprogram.org, and other training sessions as appropriate. In addition, ACUC members receive training in specific areas of animal care and use through the monthly ACUC meetings and through discussions of policy, procedure or scientific issues.
10.4 Office of Regulatory Compliance/ ACUC workshops

The Office of Regulatory Compliance provides opportunities for continuing education in the ever-evolving area of animal care and use. Seminars and workshops are announced through a variety of mechanisms; however, AGMUS Animal Care and Use Certification is always available at www.citiprogram.org.

11. OCCUPATIONAL HEALTH AND SAFETY CONCERNS: PERSONNEL HEALTH AND SAFETY

While all work in research laboratories can present dangers to laboratory personnel and students, work with animals presents special health and safety concerns. Therefore, PI's should ensure that all individuals with animal contact become knowledgeable about potential hazards and should participate in the Ana G. Mendez University System Occupational Safety and Health Program for the use of animals in research, teaching and exhibition activities of animals not part of a research proposal. In addition, individuals should be encouraged to consult their physician and/or supervisor if they have concerns or questions about their health related to the participation in animal use.

Participation in an Occupational Safety and Health Program means being familiar with the program, understanding the potential hazards, and knowing how to protect yourself and your coworkers. The elements of the program are mandatory for all the authorized employees, contractors, administrative personnel and maintenance employees that have access to the laboratories. Details of the Program are available through the Occupational Safety & Health Office. Consult the AGMUS website accessing the Administrative Affairs area under the Central Administration section, for information on Office for Occupational Safety and Health Procedures, Manuals and General information.

11.1 General Safety Issues

These include issues such as: injury prevention techniques (e.g., lifting to avoid back injury, ergonomic injuries), how to respond to fires and fire alarms, dealing with chemical spills, information available on Material Safety Data Sheets, chemical hygiene issues, and avoiding exposure to hazardous agents. Additional safety information may be obtained in the Office for Occupational Safety and Health.

11.2 Hygiene for Animal Users

Basic hygiene measures are important elements of the animal use health and safety program. Animal users can protect their health by simple common-sense actions such as washing hands promptly after animal contact and not smoking, drinking, or eating in animal areas. Assume that any material that has come from or has been in contact with
animals, including unfixed tissues or specimens, is contaminated and potentially hazardous to your health.

11.3 Zoonoses and Other Infectious Agents

Zoonotic agents are disease agents carried by animals. All animals, including laboratory animals should be considered capable of harboring and shedding bacteria, viruses, or other agents, which can cause disease in humans if exposed. Training should include a familiarity with the specific agents, which may be present and how to avoid them. Each person should consult his or her physician for personal health advice. Good hygiene and wearing protective clothing are extremely important elements of protection from zoonotic agents.

11.3.1 Injuries and Infections from Animals

Most research animals come from controlled environments and are nominally free of zoonotic infections. However, all animals have the potential for carrying infections that are transmissible to humans. Good hygiene practices minimize exposure to diseases that animals may be carrying.

When animals are handled and restrained properly, opportunities for injuries to personnel from bites and scratches are minimal. Investigators are advised to seek advice of the ACUC if they are unfamiliar with a given species of animal.

11.3.2 Other Animal Infectious Agents

All investigators are urged to discuss potential human health problems related to the use of animals before beginning work. In some quarters, instructions regarding required protective clothing are posted. These posted instructions must be followed.

11.3.3 Infections from Personnel to Animals

It is important to be aware that it is possible for humans to carry infections transmissible to laboratory animals. In some areas, instructions regarding special clothing or procedures to protect the animals from human disease contamination are posted and must be followed. Human carriers of salmonellae, mycobacterium and other zoonotic organisms should not handle any experimental animals. Please call the Occupational Safety and Health Office for further information.

11.4 Allergens

Allergies to animals are commonly associated with chronic exposure and may be serious health problems. Individuals with a history of allergies should consult their physicians for advice. All individuals should minimize exposure to allergens (hair, dander, dried urine proteins) by wearing dedicated protective clothing such as lab coats and gloves (to avoid
skin contact), avoiding unnecessary animal exposure, working with animals in well-ventilated areas, and, in some cases, by use of respiratory protection. Allergy symptoms such as skin, eye, or respiratory irritation that develop after animal exposure should prompt a consultation with a physician.

11.5 Gas Anesthetics

Gas anesthetics can be very hazardous to human and animal health. The use of an anesthetic agent on animals must be approved by the ACUC. Ether is explosive and flammable and can NEVER be used in any animal facility. It may be used in labs if precautions prescribed are followed (proper storage, use in a fume hood, etc). Other gas anesthetics must be used in a manner that minimizes human exposure: under a fume hood or with gas scavenging devices. If you can smell the anesthetic, the exposure exceeds permissible limits.

11.6 Uniforms/Clothing

Appropriate clothing must be worn whenever entering the animal facility. To enter animal facilities where special clothing requirements are in effect, follow the requirements posted. Protective clothing requirements are an important part of AGMUS’s Occupational Health and Safety Program. Investigators must take responsibility for ensuring that all staff complies with this policy. Those individuals found in repeated violations of these safety precautions will be denied access to the animal facilities.

Appropriate clothing is essential to protect research staff, as well as, reduce the possibility of transfer of pathogens from one group of animals to another. For example, the NIH/NRC Guide for the Care and Use of Laboratory Animals stipulates that a lab coat uniform worn in lab animal rooms must not be worn outside the animal facility.

11.7 Bloodborne Pathogens and "Sharps"

Individuals handling animal tissues or specimens, or using needles, surgical instruments or other sharp instruments that have been in contact with infectious material must follow the Bloodborne and Pathogen Exposure Control Plan for Ana G. Mendez University System.

11.8 Use of Hazardous Materials and Animal Use

The use of hazardous materials or agents in either animal and/or in the animal facilities must be fully described in a protocol form. Hazardous materials used in research can generally be grouped into three categories: 1) chemicals (including carcinogens); 2) radioactivity; and 3) infectious agents. Please note that in addition to the review by the ACUC, since the use of animals in studies involving hazardous agents requires special considerations, the procedures and facilities to be used must also be reviewed by the
appropriate regulatory committees (i.e., BioSafety Committee [IBC], the Occupational Safety & Health Office, etc).

Specific information on the use of hazardous materials is available both from ACUC and the IBC. For additional basic information regarding federal, state and local regulations and additional reference materials, please refer to *The Guide for the Care and Use of Laboratory Animals*. Brief introductory material on each of these subjects is included below.

**11.8.1 Working with Chemical Hazards and Animals**

Animal work involving the use of hazardous chemicals must conform to existing AGMUS policies, as well as the *NIH Guidelines for Laboratory use of Chemical Carcinogens*, the Material Safety Data Sheets and the requirements of the Centers for Disease Control. In addition, the OEHS can provide guidance on the use of certain chemicals with animals. As part of the protocol review process, the ACUC may seek guidance and recommendations from the IBC depending on the type of chemicals.

**11.8.2 Use of Radioactivity with Animals**

To utilize radioactivity (in the form of diagnostic radiography, irradiation, or radioisotopes) in animal, requires not only the approval of the ACUC, but also the approval of the Biosafety Committee. The protocol has been designed to elicit specific information about the use of hazards such as radioactivity and to ensure that approval to use radioactivity has been secured. The protocol form also ensures that the planned work will take place only in approved locations, and in accordance with standard safety policies.

The approval of an ACUC protocol may be delayed if the information is not complete or if the PI has not submitted an application for the procurement of radioisotopes and has not yet received approval by the Biosafety Committee. The ACUC may begin consideration of the animal use protocol without regard to specifics regarding radiation use; however, the ACUC will not approve a protocol until the Biosafety Committee has reviewed and approved the protocol for compliance with radiation use, storage, and disposal guidelines. Questions about the use of radioactivity may be directed to the OOHS.

**11.8.3 Working with Biohazardous Agents and Animals**

Work with biohazardous materials presents special challenges. The use of biohazardous agents must be described in full in Section XII of the ACUC Animal Study Protocol Submission Form and must receive approval from the Biosafety Committee (IBC).

Any proposed research with infectious or biohazardous materials must conform to vertebrate animal biosafety criteria as defined by the NIH/Centers for Disease Control
publication, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition*, available at [http://www.cdc.gov/od/ohs/biosfty/bmbi5/BMBL_5th_Edition.pdf](http://www.cdc.gov/od/ohs/biosfty/bmbi5/BMBL_5th_Edition.pdf). These criteria set forth the practices, safety equipment, and facilities required for approval of experimental protocols involving animals infected with agents known or believed to produce infections in humans. In addition, depending upon the agents, the proposed research, and other factors, more stringent requirements may be implemented by the ACUC and other relevant regulatory committees.

The use of biohazardous agents creates special issues for facilities and operations, employee health and safety and for animal care and use. To ensure the appropriate precautions are taken, the ACUC and IBC jointly review a protocol and may involve the relevant safety offices. Together these groups can assist in developing a plan and to determine practices, safety equipment, and facilities necessary to protect humans or other animals from inadvertent contamination. Such plans may involve protective gear, banking of serum for baseline testing, special procedures in the case of bites or needle sticks, among others. For especially dangerous substances, the committees may require that PI's develop detailed Standard Operating Procedures (SOP's) for every aspect of laboratory and research work.

11.9 **Routine Animal Handling Precautions/ Bites and other injuries**

Animal bites can be serious injuries - more often as a result of infection that from the bite itself. Report any animal bites that draws blood to your supervisor. Faculty and staff are responsible for complying with AGMUS Policy. If treatment is needed, report to Student Health Services. For more information, contact the Occupational Health and Safety Office at Ana G. Mendez University System at (787) 751-0178 Ext. 7120 or go to their website at [www.suagm.edu](http://www.suagm.edu).

Animal bites, especially those by rodents that inflict little tissue damage, are sometimes considered inconsequential by personnel who are unfamiliar with the host of diseases that can be spread by this mechanism and the complications that can result from wound contamination from the animal’s natural oral flora. Animal care providers should be aware of the need to determine their current tetanus-immunization status, seek prompt medical review of wounds and initiate veterinary evaluation of the animal if necessary. Rabies, Hantavirus infection, cat scratch fever, tularemia, and rat-bite fever are among the specific diseases that can be transmitted by animal bites with serious consequences. Physical injuries can occur through accidents in any workplace. Physical injuries inflicted directly by the animal are most likely to be serious when the animals are large - such as horses or cattle. Supervisors and instructors should make certain that the staff is adequately trained and equipped to deal with the species in question. If student lab staffs are compensated for their activities through wages or tuition reimbursement they are considered employees. Supervisors are responsible for notifying the Office of Regulatory Compliance within 24 hours of the incident.
11.10 Biohazardous Animal Disease Precautions

11.10.1 Federal Regulations for Importing Animals with Diseases

Obtaining certain biological specimens from countries or animals known to be infected with classes of diseases not found in the United States or with particularly devastating potential (e.g., anthrax) diseases requires specific USDA and U.S. Department of Public Health licensure and approval. Investigators are urged to direct inquiries on any material of this nature to the Office of Regulatory Compliance for specific consultation.

If any animal products are destined for use in live animals, this use must be identified and detailed in the protocol forms submitted for ACUC review.

11.10.2 Wild Animals

Primates and other "non-domesticated" species must always be handled with extreme caution. Animals of these species may not submit easily to handling and manipulation, and this aggressive behavior is not, by definition, vicious. The ACUC requires demonstrated experience in dealing with these species. Certain wild species may potentially pose public health problems and special requirements are necessary in order to house them. Procurement and housing of such species will involve special consideration from the Office of Regulatory Compliance.

11.11 Protocol Risk Assessment

The PI is required to complete a risk assessment on each protocol. Any training information generated as a result of the risk assessment is the responsibility of the PI to share with all students, technicians and other personnel involved with the protocol.

12. LIST OF WEBSITES WITH ADDITIONAL INFORMATION

- American Association of Laboratory Animal Science (AALAS) - http://www.aalas.org/
- Association for Assessment and Accreditation of Laboratory Animal Care (AALAC) - http://www.aalac.org/
- ARENA/PRIM&R - http://www.primr.org/
- Canadian Council on Animal Care - http://www.ccac.ca/
- Centers for Disease Control - http://www.cdc.gov/
- Guide for the Care and Use of Laboratory Animals - www//grants.nih.gov/grants/olaw/olaw.htm
- Guidelines for the Use of Wild Birds - http://www.nmnh.si.edu/BIRDNET/GuideToUse/index.html
- Institutional Animal Care and Use Committee Guidebook, ARENA -

- Office of Laboratory Animal Welfare (OLAW) -
  http://grants.nih.gov/grants/olaw/olaw.htm
- NIH Office of Extramural Research - List of Publications and Databases -
  http://grants.nih.gov/grants/documentindex.htm
- Public Health Service Policy on Humane Care and Use of Laboratory Animals -
  http://grants.nih.gov/grants/olaw/references/phspol.htm

13. References

- Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, National Institutes of Health, 2002. The